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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,944	07/16/2001	John Ernest Hart	GJE-68	6466

23557 7590 09/20/2002

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EXAMINER
AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,944	Applicant(s) Hart
	Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 9, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-6, 8, and 10-20* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6, 8, and 10-20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

V.A

DETAILED ACTION

Claims 1-6, 8 and 10-20 are pending. [Preliminary amendment, paper No. 5 filed 7/16/20015].

Claims 7 and 9 were canceled by applicant. [Preliminary amendment, paper No. 5 filed 7/16/20015].

Claim Rejections - 35 USC § 112

New matter

Claims 2, 10 and 16 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation such as "1-30 kD fraction" in the claims 2, 10 and 16 has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of making or using "1-30 kD fraction". There are some particular examples drawn to preparation of 0-30 kD molecular weight fraction and/or 10-30 kD molecular fraction by using membranes having cut off 30 kD and 10 kD (see page 6, line 10-15 and lines 23-26). This is not sufficient support for the new genus such as "1-30 kD fraction". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within

the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of limitation "1-30 kD fraction" is considered to be the insertion of new matter for the above reasons.

Indefinite

Claims 1-6, 8 and 10-20 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8 and 15 are rendered indefinite by the phrase "obtainable". This language does not point out that the source of the claimed material is critical and/or required as the language "obtained" does. Thus, it is uncertain whether/what the other source and/or characteristics of the claimed material are intended, if material is not derived from ovarian venous blood.

Claims 5, 13 and 19 are rendered indefinite because purifying protocol comprises intermediate and/final products such as "plasma cleared" or "fraction concentrated" or "elate divided", for example, rather than active steps of clearing plasma or concentrating fraction. Thus, it is uncertain what active steps, if any, are required in order to obtained the claimed material.

Claim 20 is indefinite because it is uncertain whether the mammal such as sheep is a source of "material" or "a patient in need" which under treatment with the "material".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart [IDS-AR].

Claims are directed to a material having ability to reduce organ mass, to a pharmaceutical composition with the material and to a method of administering the material to a patient in need of organ reduction.

The reference by Hart [IDS-AR] discloses clomiphene and a pharmaceutical composition with clomiphene which is having ability to reduce organ mass. It also teaches a method of administering clomiphene to a patient in need of organ reduction after hexoestrol treatment. The cited reference is considered to anticipate the claimed invention because both the cited and the claimed materials have an identical characteristic such as ability to reduce organ mass. And the claimed material is not limited to a specific source and/or a protocol of making by the virtue of indefinite phrase "obtainable".

Claims 1-3, 8, 10, 11 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,734,398 [A].

Claims are directed to a material having ability to reduce organ mass, to a pharmaceutical composition with the material and to a method for treating organ or tissue hypertrophy by administering the material to a patient in need of organ reduction wherein the material is obtained by collecting an ovarian venous blood of female mammal, preparing plasma from the ovarian venous blood, partially purifying the material from the plasma and obtaining fractions with molecular weights in the ranges 1-30 kD and/or 10-20 kD.

US 4,734,398 [A] discloses a material having ability to reduce organ mass (col. 3, line 55-58 or col. 10, lines 47, 61-64) which is obtained from ovarian venous blood of female mammal (col. 8, line 61), pharmaceutical compositions or test fractions with the material and a method for treating organ or tissue hypertrophy by administering the material to a patient in need of organ reduction (col. 9, lines 67-69 and col.10, lines 1-3). The material is obtained by steps of collecting an ovarian venous blood of female mammal (col. 8, line 63-65), preparing plasma from the ovarian venous blood by centrifugation (col. 9, lines 8, 18-19), partially purifying the material from the plasma by dialyzing with 10 kD exclusion membrane (col. 9, line 26), by chromatography and by washing with NaCl solutions (col. 9, lines 8-31). The patent teaches obtaining fractions with molecular weights in the ranges within 1-30 kD and/or 10-20 kD such as 12-15 kD, 14-18 kD, 22-25 kD which have capability of reducing organ mass or ovarian weight

(col. 4, lines 19-21 and lines 27-31; col. 11, lines 52-54). Thus, the cited patent appears to anticipate all elements of the claimed invention.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 8, 10-13 and 15-19 are rejected under 35 U.S.C. 102(b) as anticipated by US 4,734,398 [A] or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 4,734,398 [A].

Claims 1-3, 8, 10, 11 and 15-17 as explained above. Claims 4, 5 12, 13, 18 and 19 are further drawn to a protocol of purifying the ovarian venous blood derived material having ability to reduce organ mass by steps of centrifuging blood plasma to obtain fractions with molecular weights ranges 10-30 kD and 10-20 kD, eluting fractions on an ion exchange column with gradient of 0-0.3 M NaCl, obtaining and dividing the eluted fractions.

US 4,734,398 [A] is relied upon as explained above. It also teaches a protocol of purifying the ovarian venous blood derived material having ability to reduce organ mass by steps of centrifuging blood plasma, purifying the material from the plasma by dialyzing with 10 kD exclusion membrane (col. 9, line 26), eluting fractions on chromatography column with 0.5 M NaCl solution (col. 9, lines 8-31), obtaining and dividing fractions with molecular weights in the

ranges including 14-18 kD, 12-15 kD and/or 22-25 kD which have capability of reducing organ mass or ovarian weight (col. 4, lines 19-21 and lines 27-31; col. 11, lines 52-54).

The cited patent US 4,734,398 discloses material, composition with material and method of administering the material wherein the material and/or fractions appear to be identical to the presently claimed material since it was obtained from identical source such as ovarian venous blood of a mammal and it produces identical effect such as organ mass reduction when administered to a patient. The cited patent also teaches identical molecular weights or overlapping ranges of molecular weights of fractions having ability to reduce organ mass as the presently claimed fractions. Consequently, the claimed material, composition with material and method of administering the material appear to be anticipated by US 4,734,398.

In the alternative, even if the claimed material and/or fractions are not identical to the referenced material/fractions with regard to some unidentified characteristics related to the use of particular ion exchange chromatography columns or specific concentrations of NaCl, for example, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced material and/or fractions are likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share such identical source, identical effects and identical molecular weights. Thus the claimed material, composition with material and method of administering the material would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by US 4,734,398, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1-6, 8 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,734,398 [A].

Claims 1-5, 8, 10-13 and 15-19 as explained above. Claims 6, 14 and 20 are further drawn to the use of sheep as source of mammalian ovarian venous blood for obtaining material having ability to reduce organ mass.

US 4,734,398 [A] is relied upon as explained above. The particular example discloses humans as source of mammalian ovarian venous blood for obtaining material/fractions having ability to reduce organ mass. But the cited patent also teaches that these materials/fractions are proteins (col. 8, line 61 and col. 10, last line) and that the activity of proteins is interspecies and that it is both produced and effective in monotocous and polytocous mammals (col. 3, line 29).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain material/fractions having ability to reduce organ mass from various mammals including human and sheep with a reasonable expectation of success in obtaining proteins fractions effective for reducing organ mass or for treating organ or tissue hypertrophy because activity of similar proteins is interspecies and similar effective proteins are produced in monotocous mammals or mammals producing mainly one young such as humans, for example, and in polytocous mammals or mammals producing several youngs such as sheep,

for example. One of skill in the art would have ben motivated to use various mammals including sheep as the source of therapeutically valuable materials for the benefits of obtaining drugs suitable for reducing organ mass or for treating organ or tissue hypertrophy.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

Art Unit 1651

September 13, 2002.

IRENE MARX

PRIMARY EXAMINER